

Form PTO-1449 (modified)		Atty. Docket No. ILEX:053US	Serial No. 09/938,846
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Frank L. Meyskens, Jr. <i>et al.</i>	
		Filing Date: August 24, 2001	Group: 1623
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 1</i>	Other Art <i>See Page 1</i>	

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
JDA	A1	4,330,559	5/18/82	Bey <i>et al.</i>	424	319	2/3/81
JDA	A2	4,413,141	11/1/83	Bey <i>et al.</i>	562	561	9/17/82
JDA	A3	4,499,072	2/12/85	Sunkara <i>et al.</i>	424	85	1/24/83
JDA	A4	4,859,452	8/22/89	Ajani <i>et al.</i>	424	10	1/13/87
JDA	A5	4,925,835	5/15/90	Heston	514	183	10/26/87
JDA	A6	5,002,879	3/26/91	Bowlin <i>et al.</i>	435	71.1	12/5/89
JDA	A7	6,277,411 B1	7/10/01	Gerner <i>et al.</i>	514	544	3/26/99
JDA	A8	6,258,845 B1	8/21/01	Shaked <i>et al.</i>	424	489	12/11/98

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
JDA	C1	Auvinen, "Cell transformation, invasion and angiogenesis: a regulatory role for ornithine decarboxylase and polyamines?" <i>J. Nat'l Cancer Inst.</i> , 89:533-537, 1997.
JDA	C2	Brawn <i>et al.</i> , "Prostatic acid phosphatase levels (enzymatic method) from completely sectioned, clinically benign, whole prostates," <i>The Prostate</i> , 28: 295-299, 1996.
JDA	C3	Carbone <i>et al.</i> , "Phase I chemoprevention study of piroxicam and alpha-difluoromethylornithine." <i>Cancer Epidemiol Biomarkers Prev</i> 7(10): 907-912, 1998.
JDA	C4	Carter <i>et al.</i> , "Prostate-specific membrane antigen is a hydrolase with substrate and pharmacologic characteristics of a neuropsptidase," <i>Proc. Nat'l Acad. Sci. USA</i> 93: 749-753, 1996.
JDA	C5	Clifford <i>et al.</i> , "Role of ornithine decarboxylase in epidermal tumorigenesis," <i>Cancer Res.</i> , 55:1680-1686, 1995.

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Exam. Init.	Ref. Des.	Citation
JDA	C6	Cote <i>et al.</i> , "The effect of finasteride on the prostate gland in men with elevated serum prostate specific antigen levels," <i>Br. J. Cancer</i> , 78(3):413-418, 1998.
	C7	Croghan <i>et al.</i> , "Dose-related $\alpha$ -difluoromethylornithine ototoxicity," <i>Am. J. Clin. Oncol.</i> , (14):331-335, 1991.
	C8	Danzin <i>et al.</i> , "Effect of $\alpha$ -difluoromethylornithine, an enzyme-activated irreversible inhibitor of ornithine decarboxylase, on polyamine levels in rat tissues," <i>Life Sci.</i> , 24:519-524, 1979.
	C9	Danzin <i>et al.</i> , "Effects of $\alpha$ -difluoromethylornithine, an enzyme-activated irreversible inhibitor of ornithine decarboxylase, on testosterone-induced regeneration of prostate and seminal vesicle in castrated rats," <i>Biochem. J.</i> , 180:507-513, 1979.
	C10	Dunzendorfer and Russell, "Altered polyamine profiles in prostatic hyperplasia and in kidney tumors," <i>Cancer Res.</i> , 38:2321-2324, 1978.
	C11	Feuer <i>et al.</i> , "Cancer surveillance series: interpreting trends in prostate cancer-part II: Cause of death misclassification and the recent rise and fall in prostate cancer mortality," <i>J. Nat'l Cancer Inst.</i> , 91(12):1025-1032, 1999.
	C12	Gerner <i>et al.</i> , "Gastrointestinal tissue polyamine contents of patients with Barretts esophagus treated with difluoromethylornithine," <i>Cancer Epidemiol. Biomarkers Prev.</i> , 3:325-330, 1994.
	C13	Heston <i>et al.</i> , "Copenhagen rat prostatic tumor ornithine decarboxylase activity (ODC) and the effect of the ODC inhibitor $\alpha$ -difluoromethylornithine," <i>The Prostate</i> , 3:383-389, 1982.
	C14	Jacoby <i>et al.</i> , "Chemopreventive efficacy of combined piroxicam and difluoromethylornithine treatment of Apc mutant Min mouse adenomas, and selective toxicity against Apc mutant embryos," <i>Cancer Research</i> , 60(7): 1864-1870, 2000.
	C15	Kergozien, "Polyamine deprivation provokes an antalgic effect," <i>Life Sci.</i> , 58(24):2209-2215, 1996.
✓	C16	Kubota <i>et al.</i> , "Ornithine decarboxylase overexpression in mouse 10T1/2 fibroblasts: cellular transformation and invasion," <i>J. Nat'l Cancer Inst.</i> , 89:567-571, 1997.
JDA	C17	Kulkarni <i>et al.</i> , "Effect of the chemopreventive agents piroxicam and D,L- $\alpha$ -difluoromethylornithine on intermediate biomarkers of colon carcinogenesis," <i>Carcinogenesis</i> , 13:995-1000, 1992.

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JDA	C18	Levin <i>et al.</i> , "Phase I-II study of eflornithine and mitogauzone combined in the treatment of recurrent primary brain tumors," <i>Cancer Treat. Rep.</i> , 71:459-464, 1987.
	C19	Li <i>et al.</i> , "Prevention by aspirin and its combination with alpha- difluoromethylornithine of azoxymethane-induced tumors, aberrant crypt foci and prostaglandin E2 levels in rat colon." <i>Carcinogenesis</i> 20(3): 425-430, 1999.
	C20	McCann and Pegg, "Ornithine decarboxylase as an enzyme target for therapy," <i>Pharmacol. Ther.</i> , 54:195-215, 1992.
	C21	Messing <i>et al.</i> , "Low dose difluoromethylornithine and polyamine levels in human prostate tissue," <i>J. Natl Cancer Inst.</i> , 91(16):1416-1417, 1999.
	C22	Meyskens and Gerner, "Development of difluoromethylornithine (DFMO) as a chemopreventive agent," <i>Clin. Cancer Res.</i> , 5:945-951, 1999.
	C23	Meyskens <i>et al.</i> , "A phase II study of $\alpha$ -difluoromethylornithine (DFMO) for the treatment of metastatic melanoma," <i>Invest. New Drugs</i> , (4):257-262, 1986.
	C24	Meyskens <i>et al.</i> , "Dose de-escalation chemoprevention trial $\alpha$ -difluoromethylornithine in patients with colon polyps," <i>J. Natl Cancer Inst.</i> , 86(15):1122-1130, 1994.
	C25	Meyskens <i>et al.</i> , "Effect of difluoromethylornithine on rectal mucosal levels of polyamines in a randomized, double-blind trial for colon cancer prevention" <i>J. Natl. Cancer Inst.</i> , 90(16):1212-1218, 1998.
	C26	Mitchell <i>et al.</i> , "Polyamine measurements in the uterine cervix," <i>J. Cell Biochem Suppl.</i> , 28/29:125-132, 1997.
	C27	Mohan <i>et al.</i> , "Over-expression of ornithine decarboxylase in prostate cancer and prostatic fluid in humans," <i>Clin. Cancer Res.</i> , 5:143-147, 1999.
	C28	Moulinoux <i>et al.</i> , "The growth of MAT-LyLu rat prostatic adenocarcinoma can be prevented <i>in vivo</i> by polyamine deprivation," <i>J. Urol.</i> , 146:1408-1412, 1991.
	C29	Nigro <i>et al.</i> , "Importance of the duration of inhibition on intestinal carcinogenesis by difluoromethylornithine in rats," <i>Cancer Lett.</i> , 35:153-158, 1987.
↓	C30	Nowels <i>et al.</i> , "Prevention of the inhibitory effects of alpha-difluoromethylornithine on rat urinary bladder carcinogenesis by exogenous putrescine," <i>Cancer. Biochem. Biophys.</i> , 8:257-263, 1986.

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JDA	C31	Pegg, "Polyamine metabolism and its importance in neoplastic growth and a target for chemotherapy," <i>Cancer Res.</i> , 48:759-774, 1988.
	C32	Pienta <i>et al.</i> , "Phase II chemoprevention trial of oral fenretinide in patients at risk for adenocarcinoma of the prostate," <i>Am. J. Clin Oncol.</i> , 20(1):36-39, 1997.
	C33	Reddy <i>et al.</i> , "Chemoprevention of colon carcinogenesis by concurrent administration of piroxicam, a nonsteroidal anti-inflammatory drug with D,L- $\alpha$ -difluoromethylornithine, and ornithine decarboxylase inhibitor, in diet," <i>Cancer Res.</i> , (50):2562-2568, 1990.
	C34	Singh <i>et al.</i> , "Intermediate biomarkers of colon cancer, modulation of expression of ras oncogene by chemopreventive agents during azoxymethane induced colon carcinogenesis," <i>Carcinogenesis</i> , 14:669-704, 1993.
	C35	Thompson <i>et al.</i> , "Effect of concentration of D,L-2-Difluoromethylornithine on murine mammary carcinogenesis," <i>Cancer Res.</i> , 45:1170-1173, 1985.
	C36	Verma, "Inhibition of tumor promotion by DL-alpha-difluoromethylornithine, specific irreversible inhibitor of ornithine decarboxylase," <i>Basic Life Sci.</i> , 52:195-204, 1990.
	C37	Wallon <i>et al.</i> , "Polyamine-dependent expression of the matrix metalloproteinase matrilysin in a human colon cancer cell line," <i>Mol. Carcinog.</i> , 11:138-144, 1994.
	C38	Weeks <i>et al.</i> , " $\alpha$ - Difluoromethylornithine, an irreversible inhibitor of ornithine decarboxylase, inhibits tumor promoter-induced polyamine accumulation and carcinogenesis in mouse skin," <i>Proc. Nat'l Acad. Sci. U.S.A.</i> , (79):6028-6032, 1982.
JDA	C39	Co-pending U.S. Patent Application Serial Number 09/801,197 filed March 6, 2001.

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